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Outcomes of vaginal breech delivery for singleton term pregnancies in a carefully selected Cameroonian population: a cohort study

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- 1 Title:
- 2 Outcomes of vaginal breech delivery for singleton term pregnancies in a carefully selected
- 3 Cameroonian population: a cohort study.
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- 24 Abstract
- **Background and objectives:** Vaginal breech delivery (VBD) is known to be associated with
- 26 more perinatal complications. Very few studies on the subject have been carried out in poor
- 27 resource settings. The aim of this study was to determine maternal and neonatal outcomes in
- 28 carefully selected cases of VBD for singleton term pregnancies in a tertiary centre in
- 29 Cameroon.
- **Design:** A retrospective cohort study
- **Setting:** A tertiary hospital in Yaounde (Centre region of Cameroon)
- Participants: Cases of VBD of newborns weighing 2500 3500g were matched in a ratio of
- 1:4 to consecutive vaginal cephalic deliveries (VCD) of newborns weighing 2500 3500g
- over a five-year period. Both groups were matched for maternal age and parity. We excluded
- 35 cases of multiple gestations, footling breech, clinically inadequate maternal pelvis, preterm
- delivery, delivery after 41 weeks of gestation, foetal demise prior to the onset of labour,
- 37 placenta praevia and foetal anomaly incompatible with vaginal delivery.
- 38 Outcome measures: Neonatal and maternal adverse outcomes of VBD observed till six
- 39 weeks after delivery. Bonferroni adjusted p-values were calculated in order to reduce the
- 40 chance of obtaining false-positive results.
- **Results:** Fifty-three (53) VBD were matched against 212 VCD. Women who underwent
- 42 VBD were were three-fold more likely to have prolonged labour (p=0.000001), four-fold
- more likely to have meconium stained amniotic fluid (p=0.000001), and their newborns were
- about five-fold as likely to suffer from birth asphyxia (p=0.000001).
- 45 Conclusion: When specific protocols are applied, VBD of singleton term pregnancies is still
- associated with adverse outcomes in this setting. This finding does not discount the role of
- VBD in low-income countries, but we emphasize the need for specific precautions like close
- 48 monitoring of labour and adequate anticipation for neonatal resuscitation in order to reduce
- 49 these complications.

Keywords: breech, vaginal delivery, cephalic presentation, singleton term pregnancies,outcome, Cameroon.

Strengths and limitations:

- The use of guidelines to select cases of vaginal breech delivery in order to decrease the risk of selection bias in the findings obtained.
- Bias was further reduced by calculating Bonferroni adjusted p-values.
- The study had a retrospective nature of data collection, which was subject to a
 potential risk of incorrectly completed records.
- The study was carried out in a single centre with standards of a tertiary level of care, which implies cautious generalization of results to health facilities not having the same level of care.

Introduction:

- Breech presentations represent 3 4% of all foetal presentations at term [1]. Vaginal breech deliveries (VBD) are associated with a ten-fold increase in perinatal mortality when compared to vaginal cephalic deliveries (VCD) [2].
 - The safest mode of delivery in case of breech presentation has long been a debate in obstetrics [3]. It is recommended to carry out elective caesarean section rather than vaginal delivery for singleton term breech pregnancies when there is foetal distress, macrosomia, footling breech presentation, clinically inadequate maternal pelvis, growth-restricted baby, placenta praevia or foetal anomaly incompatible with vaginal delivery, or if an experienced clinician is absent or the clinician lacks adequate expertise for VBD [4–6]. Evidence abounds that unlike VBD for singleton term pregnancies, elective caesarean section reduces perinatal mortality and morbidity, as well as maternal morbidity (urinary incontinence and postpartum perineal pains) in developed countries [7]. However, in developing countries, the outcomes of

both VBD and elective caesarean breech delivery appear comparable [7], possibly due to the prevailing expertise of birth attendants in VBD in these resource-challenged settings [3]. Furthermore, it has been shown that as much as 39 caesarean sections are required to prevent one neonatal death or adverse neonatal outcome in low-income countries compared to seven caesarean sections needed in high-income settings [3]. Hence, a health policy generalizing the indication of caesarean section to all breech presentations in low-income countries would require significant additional investments in their health care systems. Also, the presence of a scarred uterus puts subsequent pregnancies at increased risk of complications such as placenta praevia, placenta accreta and placenta abruption, uterine rupture, repeat caesarean section and repeat breech presentation [8–10]. Likewise, elective caesarean section for breech presentation cannot be performed in all resource-limited settings due to its financial cost and the prevalent inadequate surgical infrastructure in most health facilities [7].

As such, external cephalic version for singleton term pregnancies has been recommended as a safe and cost-effective means to revert breech to cephalic presentation and avert the resort to either VBD or caesarean sections [11]. However, external cephalic version is not routinely performed in clinical practice because many health personnel lack its mastery or unduly perceive it to be associated with adverse perinatal outcomes [12]. Thus, vaginal delivery is still the main route of delivery in resource-limited environments. Data on vaginal breech delivery for singleton term pregnancies in sub-Saharan Africa is scarce, thus, explaining the lack of consensus on the management of this foetal presentation in the continent. The aim of this study was to investigate the maternal and neonatal outcomes of vaginal delivery of singleton term foetus in breech presentation following strict selection criteria in a tertiary centre of Cameroon.

Materials and Methods

Study design and setting

In this cohort study, we retrospectively reviewed all pregnant women at term who had a VBD and pregnant women at term with VCD at the maternity of the Yaounde Gynaeco-Obstetric and Pediatric Hospital (YGOPH) between 1st January 2012 to 31st December 2016. The YGOPH is a tertiary hospital located in Yaoundé, the political capital of Cameroon. This health facility serves as a major referral centre for mother and child care in Yaounde and its environs. In this hospital, it is a policy for an experienced obstetrician to be present for every vaginal breech delivery.

Participants, sampling and follow-up.

The selection criteria used for cases of VBD were described in guidelines of the International Federation of Obstetricians and Gynaecology[6], the Royal College of Obstetricians and Gynaecologists [5], and the Society of Obstetricians and Gynaecologists of Canada [4]. Each case of VBD of newborn weighing 2500 – 3500g was matched for maternal age and parity to four consecutive VCD of newborns weighing 2500 – 3500g. We excluded all pregnant women with multiple gestations, footling breech presentation, clinically inadequate maternal pelvis, preterm delivery (fewer than 37 weeks of gestation), pregnancies older than 41 weeks, known cases of foetal demise prior to the onset of labour. Additional exclusion criteria were the presence of a major foetal congenital anomaly (like anencephaly, congenital heart diseases, hydrocephalus), or if there was a contraindication to vaginal delivery such as placenta praevia. In both VBD and VCD groups, we excluded cases of vaginal delivery converted to caesarean delivery. In both groups, women and their newborns were retrospectively followed-up till six weeks after delivery, corresponding to the end of the puerperal period for women and the next vaccination schedule for newborns.

Data collection and variables.

- From the delivery registers and the neonatal discharge chart respectively, all term singleton breech deliveries and all term breech delivered babies transferred to the neonatal unit were identified. Their medical records were then retrieved from the hospital archives for data extraction. The variables studied were:
- Maternal demographic data: maternal age, marital status and profession.
 - Obstetric history: parity, number of antenatal care visits and follow-up of pregnancy
 - Details of labour: foetal presentation, foetal heart rhythm, premature rupture of membranes, umbilical cord prolapse, uterine contractions, colour of amniotic fluid, duration of labour, episiotomy, perineal tears, APGAR score at the 5th minute and birth injuries, perinatal deaths.
 - Follow-up data: the occurrence of postpartum haemorrhage, urinary or faecal incontinence in women, and perinatal mortality for newborns.

Data management and statistical analysis

Data was entered in Epi Info 7.1.3.3 software. Comparison of variables between pregnant women who had VBD and VCD was done using the Chi-square test or Fisher exact test where appropriate. Relative risks (RR) and their corresponding 95% confidence intervals (95% CI) were calculated in order to measure associations. The original alpha-value was set at 0.05. In order to reduce the chance of obtaining a false-positive results from the multiple analyses performed on the same dependent variable, Bonferroni adjusted p-values were calculated by dividing the alpha-value by the number of comparisons. Hence, any comparison was statistically significant if it was inferior to the Bonferroni adjusted p-value. Patients lost of follow-up were excluded from the final analysis. Also, variables with too much missing

data precluding meaningful analyses were excluded.

Ethical consideration

The study was approved by the Institutional Review Board of the Faculty of Medicine and

Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon.

Results

Demographic and obstetrical characteristics

During the five-year review period, a total of 13, 695 deliveries were recorded. Among these deliveries, 364 breech deliveries occurred, giving an incidence of 26.6 per 1000 deliveries. After strict application of our eligibility criteria, we retained the files of 53 women with singleton term vaginal breech deliveries of babies weighing between 2500 - 3500g (Figure 1). These women were matched to 212 women with singleton term VCD of newborns weighing between 2500 - 3500g during the same study period. There were 35 frank breech presentations (66%) and complete breech in 18 cases (34%). The maternal ages ranged from 15 to 45 years and the most frequent age group was 26 – 35 years (51.3%). Half had attended at least four antenatal care visits, 54.7% were unemployed and 45.3% were married (table 1).

Maternal outcomes

Unlike pregnant women who had VCD, those who underwent VBD were about twice as likely to have premature rupture of membranes (p=0.0337), three-fold more likely to have prolonged labour (p=0.000001), four-fold more likely have meconium stained amniotic fluid (p=0.000001) and two-fold more likely to have postpartum haemorrhage (p=0.0124). After

Bonferroni adjustment (p-value < 0.00625), only prolonged labour and meconium stained amniotic fluid were retained as adverse maternal outcomes of VBD (table 2).

Neonatal outcomes

Compared to babies born of VCD, those delivered through VBD were twice as likely to have foetal distress (p=0.0153), were about four-fold more likely to have brachial plexus injury (p=0.0262) and about five-fold as likely to suffer from birth asphyxia (p=0.000001). Only birth asphyxia was retained as an adverse neonatal outcome after Bonferroni correction (p < 0.0125) (table 3).

Discussion

This study aimed at determining the maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in a referral mother and child hospital in the capital city of Cameroon. We found that pregnant women undergoing VBD were more likely to have prolonged labour (p=0.000001) and meconium stained amniotic fluid (p=0.000001), while their newborns were more likely to suffer from birth asphyxia (p=0.000001).

The eligibility criteria were, singleton term live breech foetus with normal birth weight (2500 – 3500g) and absence of the following criteria; multiple gestations, footling breech presentation, preterm delivery, pregnancies older than 41 weeks, foeto-pelvic disproportion, major or lethal foetal congenital anomaly (like anencephaly, congenital heart diseases, hydrocephalus), foetal demise prior to the onset of labour and other contraindications to vaginal delivery such as placenta praevia. Despite the application of these criteria in the selection of cases, VBD was found to be significantly associated with prolonged labour, meconium stained amniotic fluid and birth asphyxia. Our observation could be the result of the high incidence of dystocia associated with this presentation.

The findings in this study indicate that the perinatal mortality in VBD was comparable to that of VCD (2% vs 0%; p=0.2). This may be attributed to the fact that the study was carried out in referral hospital with an experienced obstetric team and with means of electronic foetal monitoring (cardiotocography) to timely detect warning signs during vaginal breech birth. These results are consistent with the studies reporting no difference in the perinatal mortality following breech delivery in resource-limited settings [13,14]. On the other hand, Kemfang et al [15] in a similar study setting in Cameroon reported a significant perinatal mortality (p<0.01) for breech deliveries, which could be due to the absence of well-defined selection criteria for vaginal breech delivery in their series. Their observed perinatal mortality was in cases of macrosomia, nuchal extension, dystocic labour and placental abruption, which were all excluded in the current cohort.

Babies born through VBD were more likely to have birth asphyxia than those who had a vaginal cephalic birth (47% vs. 8%; p = 0.000001), corroborating previous studies from both high-income [3,16] and low-income settings [13,14,17]. This could be related to the fact that breech foetuses face an increased risk of hypoxic-anoxic events from head entrapment, rapid decompression of the head, and other birth trauma [7].

The main limitation of this study is its retrospective nature of data collection, which was subject to a potential risk of incorrectly completed records. Also, the study was conducted in an urban centre with standards of a tertiary level of care, which implies cautious generalization of our results to health facilities not having the same level of care in rural settings. Nevertheless, based on careful selection criteria of singleton term VBD and a robust statistical analysis to eliminate bias, we reviewed a five-year period to assess the outcomes of VBD in a low-income country where caesarean delivery cannot be generalized as the route of delivery for all breech presentations because of its financial cost and the prevalent inadequate

surgical infrastructure in most health facilities. Our finding is a significant contribution to the on-going debate on the safety of vaginal breech delivery in sub-Saharan Africa.

Conclusion

- Our findings suggest when breech delivery guidelines are applied, VBD of singleton term pregnancies is still associated with a three-fold risk of prolonged labour, a four-fold risk of meconium stained amniotic fluid, and a five-fold risk of birth asphyxia. This finding does not discount the role of VBD in resource-poor settings, but we emphasize the need for specific precautions like close monitoring of labour and adequate anticipation for neonatal resuscitation in order to reduce these complications. Also, elective caesarean section should be performed for singleton breech term pregnancies whenever possible. This would need to be further explored in large multicentre clinical trials in our resource-constrained settings.
- **Acknowledgments:** The authors express their gratitude to the administrative authorities of the Yaounde Gynaeco-Obstetric and Paediatric Hospital for granting them permission to conduct this study.
- Authors' contributions: JSD, PF and EM: Study conception and design, acquisition of data, data analysis and interpretation, manuscript writing and critical revisions. FM: Study conception and design, acquisition of data, data analysis and interpretation and manuscript writing. JNT, MNT, RT and VA: Acquisition of data, data analysis and interpretation, manuscript writing and revisions. All authors read and approved the final manuscript.
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- 236 Competing interests: We have read and understood BMJ policy on declaration of interests
- and declare that we have no competing interests.
- 238 Ethical Approval: The study was approved by the Institutional Review Board of the Faculty
- of Medicine and Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon.
- **Data sharing statement:** Data available from the following Dryad Digital Repository;
- 241 http://dx.doi.org/10.5061/dryad.cf3mp

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Figure and Table Legend

- Figure 1: Flow chart depicting selection of vaginal breech delivery cases.
- Table 1: Socio-demographic characteristics and obstetric history of mothers
- Table 2: Maternal outcomes of vaginal breech delivery
- Table 3: Analysis of neonatal outcomes associated with vaginal breech delivery

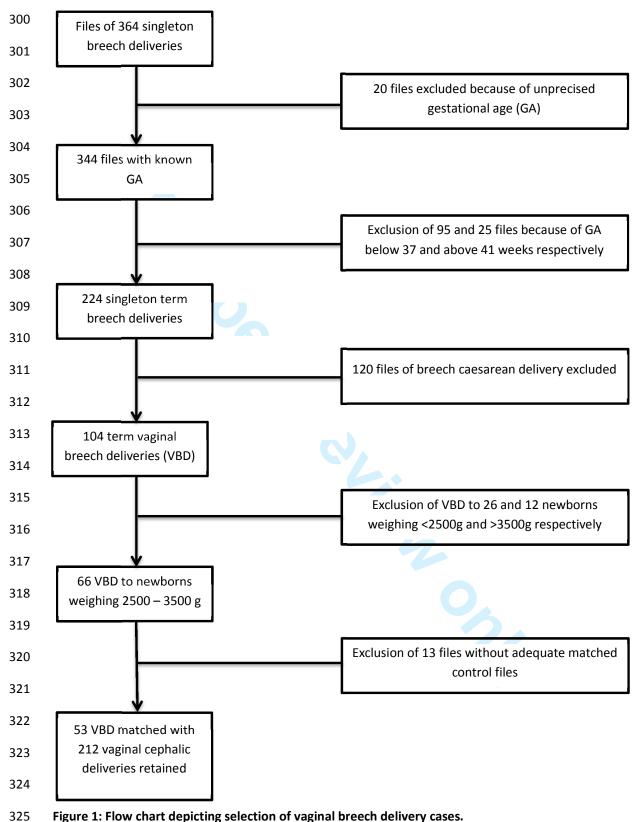


Figure 1: Flow chart depicting selection of vaginal breech delivery cases.

Table 1: Socio-demographic characteristics and obstetric history of mothers

Groups	Number	Frequency (%)
Maternal age groups (N=265) (years)		
15 - 25	99	37.4
26 - 35	136	51.3
35 - 45	30	11.3
Type of breech presentation (N=53)		
Frank breech	35	66
Complete breech	18	34
Occupation (N=265)		
Unemployed	145	54.7
Employed	72	27.2
Self-employed	48	18.1
Marital status (N=264)		
Married	120	45.3
Single	117	44.2
Cohabitation	27	10.2
Parity (N=265)	2,	10.2
Nulliparous (parity = 0)	104	39.3
Primiparous (parity = 1)	60	22.6
Multiparous (parity > 1)	101	38.1
Number of antenatal care visits (N=262)	101	50.1
≥ 4	135	51
< 4	127	48

341 Table 2: Maternal outcomes of vaginal breech delivery

Variables	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	Relative risk	95% confidence interval	p-value
Premature rupture of					
membranes					
Yes	13 (24.5%)	28 (13%)	1.77	1.04-3.02	0.0337
No	40 (75.5%)	184 (87%)	1.//	1.04 3.02	0.0557
Meconium stained amniotic	40 (73.370)	104 (0770)			
fluid					
Yes	13 (24.5%)	5 (2.4%)	4.46	2.98-6.67	0.000001
No	40 (75.5%)	207 (97.6)	1.10	2.90 0.07	0.000001
Umbilical cord prolapse	40 (73.370)	207 (77.0)			
Yes	2 (4%)	1 (0.5%)	3.42	1.48-7.91	0.1029
No	51 (96%)	211 (99.5%)	3.12	1.10 7.51	0.1029
Prolonged labour (> 12	31 (5070)	211 (55.570)			
hours)					
Yes	25 (47%)	28 (13%)	3.57	2.28-5.58	0.000001
No	28 (53%)	184 (87%)	3.57	2.20 2.50	0.000001
Episiotomies	20 (3370)	101 (0770)			
Yes	3 (5.7%)	22 (10.4%)	0.57	0.19-1.71	0.4312
No	50 (94.3%)	190 (89.6%)	0.57	0.17 1.71	0.1312
Perineal tears	20 (21.270)	190 (09.070)			
Yes	17 (32%)	64 (30%)	1.07	0.64-1.79	0.7897
No	36 (68%)	148 (70%)	1.07	0.01 1.75	0.7057
Uterine atony	30 (0070)	110 (7070)			
Yes	1 (2%)	5 (2.4%)	0.83	0.13-5.05	1.0000
No	52 (98%)	207 (97.6%)	0.05	3.12 2.03	1.0000
Postpartum haemorrhage	32 (30,0)	207 (57.070)			
Yes	7 (13.2%)	10 (4.7%)	2.21	1.18-4.14	0.0124
No	46 (86.8%)	202 (95.3%)		1.10 1.11	
Bonferroni corrected p-valu	\ /	- (, -)			

Bonferroni corrected p-value < 0.00625.

Table 3: Analysis of neonatal outcomes associated with vaginal breech delivery

	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	Relative risk	95% confidence interval	p-value
Foetal distress	()	()			
Yes	9 (17%)	15 (7%)	2.05	1.14-3.67	0.0153
No	44 (83%)	197 (93%)			
Neonatal asphyxia	,	, ,			
Yes	25 (47.2%)	17 (8.0%)	4.74	3.09-7.26	0.000001
No	28 (52.8%)	195 (92%)			
Brachial plexus injury	,	,			
Yes	3 (5.7%)	01(0.5%)	3.91	2.11-7.26	0.0262
No	50 (94.3%)	211 (99.5%)			J - J -
Perinatal deaths	2 3 (2 2 / 3)	(>>, 3)			
Yes	1 (2%)	00	5.07	3.98-6.47	0.2
No	52 (98%)	212 (100%)	2.07	3.50 0.17	0.2

Bonferroni corrected p-value < 0.0125.

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 3 and 4
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4
Methods			
Study design	4	Present key elements of study design early in the paper	Page 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pages 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Page 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6
Bias	9	Describe any efforts to address potential sources of bias	Page 6
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 6
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	Page 6
		(d) If applicable, explain how loss to follow-up was addressed	Page 6
		(e) Describe any sensitivity analyses	-
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed	Page 7 and 13
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	Page 7 and 13
		(c) Consider use of a flow diagram	Page 13
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 7 and 14
		(b) Indicate number of participants with missing data for each variable of interest	Page 7 and 13
		(c) Summarise follow-up time (eg, average and total amount)	Page 7
Outcome data	15*	Report numbers of outcome events or summary measures over time	Pages 7 and 8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	Pages 7, 8, 15 and 16
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 8
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	Pages 8 and 9
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	Not applicable
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in a carefully selected Cameroonian population: a cohort study.

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- 1 Title:
- 2 Maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in
- a carefully selected Cameroonian population: a cohort study.
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24 Abstract

- **Background and objectives:** Vaginal breech delivery (VBD) is known to be associated with
- 26 more perinatal and maternal complications. Very few studies on the subject have been carried
- out in poor resource settings. The aim of this study was to determine maternal and neonatal
- 28 outcomes in carefully selected cases of VBD for singleton term pregnancies in a tertiary
- 29 centre in Cameroon.
- **Design:** A retrospective cohort study
- **Setting:** A tertiary hospital in Yaounde, Cameroon
- Participants: Cases of VBD of newborns weighing 2500 3500g were matched in a ratio of
- 33 1:4 to consecutive vaginal cephalic deliveries (VCD) of newborns weighing 2500 3500g
- over a five-year period. Both groups were matched for maternal age and parity. We excluded
- 35 cases of multiple gestations, footling breech, clinically inadequate maternal pelvis, preterm
- delivery, post term pregnancies, foetal demise prior to the onset of labour, placenta praevia
- and foetal anomaly incompatible with vaginal delivery.
- 38 Outcome measures: Neonatal and maternal adverse outcomes of VBD observed till six
- 39 weeks after delivery analysed using Bonferroni correction.
- **Results:** Fifty-three (53) VBD were matched against 212 VCD. Unlike women who had
- VCD, those who underwent VBD were more likely to have prolonged labour (OR: 8.05; 95%
- 42 CI: 3.00-11.47; p <0.001), emission of meconium stained amniotic fluid (OR: 13.45; 95% CI:
- 43 4.54-39.84; p <0.001), and their newborns were more likely to suffer from birth asphyxia
- 44 (OR: 10.24; 95% CI: 4.92-21.31; p < 0.001).
- 45 Conclusion: The study infers a strong association between VBD of singleton term
- 46 pregnancies and maternofoetal morbidity when specific protocols are applied. This however,
- 47 failed to translate into higher differences in perinatal mortality. This finding does not discount
- 48 the role of VBD in low-income countries, but we emphasize the need for specific precautions
- 49 like close monitoring of labour and adequate anticipation for neonatal resuscitation in order
- to reduce these complications.

Keywords: breech, vaginal delivery, cephalic presentation, singleton term pregnancies, outcome, Cameroon.

Strengths and limitations:

- The use of guidelines to select cases of vaginal breech delivery in order to decrease the risk of selection bias in the findings obtained.
- Bias was further reduced by calculating Bonferroni adjusted p-values.
- The study had a retrospective nature of data collection, which was subject to a potential risk of incorrectly completed records.
- The study was carried out in a single centre with standards of a tertiary level of care, which implies cautious generalization of results to health facilities not having the same level of care.

Introduction:

- Breech presentations represent 3 4% of all foetal presentations at term [1]. Vaginal breech deliveries (VBD) are associated with a ten-fold increase in perinatal mortality when compared to vaginal cephalic deliveries (VCD) [2].
 - The safest mode of delivery in case of breech presentation has long been a debate in obstetrics [3]. It is recommended to carry out elective caesarean section rather than vaginal delivery for singleton term breech pregnancies when there is foetal distress, macrosomia, footling breech presentation, clinically inadequate maternal pelvis, growth-restricted baby, placenta praevia or foetal anomaly incompatible with vaginal delivery, or if an experienced clinician is absent or the clinician lacks adequate expertise for VBD [4–6]. Evidence abounds that unlike VBD for singleton term pregnancies, elective caesarean section reduces perinatal mortality and morbidity, as well as maternal morbidity (urinary incontinence and postpartum perineal pains) in developed countries [7]. However, in resource-limited countries, the

outcomes of both VBD and elective caesarean breech delivery appear comparable [7], possibly due to the prevailing expertise of birth attendants in VBD in these resource-challenged settings [3]. Furthermore, it has been shown that as much as 39 caesarean sections are required to prevent one neonatal death or adverse neonatal outcome in low-income countries compared to seven caesarean sections needed in high-income settings [3]. Hence, a health policy generalizing the indication of caesarean section to all breech presentations in low-income countries would require significant additional investments in their health care systems. Also, the presence of a scarred uterus puts subsequent pregnancies at increased risk of complications such as placenta praevia, placenta accreta and placenta abruption, uterine rupture, repeat caesarean section and repeat breech presentation [6,8–11]. Likewise, elective caesarean section for breech presentation cannot be performed in all resource-limited settings due to its financial cost and the prevalent inadequate surgical infrastructure in most health facilities [7].

As such, external cephalic version for singleton term pregnancies has been recommended as a safe and cost-effective means to revert breech to cephalic presentation and avert the resort to either VBD or caesarean sections [12]. However, external cephalic version is not routinely performed in clinical practice because many health personnel lack its mastery or unduly perceive it to be associated with adverse perinatal outcomes [13]. Thus, vaginal delivery is still the main route of delivery in resource-limited environments. Data on vaginal breech delivery for singleton term pregnancies in sub-Saharan Africa is scarce, thus, explaining the lack of consensus on the management of this foetal presentation in the continent. The aim of this study was to investigate the maternal and neonatal outcomes of vaginal delivery of singleton term foetus in breech presentation following strict selection criteria in a tertiary centre of Cameroon.

Materials and Methods

Study design and setting

In this cohort study, we retrospectively reviewed case notes of all pregnant women at term who had a VBD and pregnant women at term with VCD at the maternity of the Yaounde Gynaeco-Obstetric and Pediatric Hospital (YGOPH) between 1st January 2012 to 31st December 2016. The YGOPH is a tertiary hospital located in Yaoundé, the political capital of Cameroon. This health facility serves as a major referral centre for mother and child care in Yaounde and its environs. The maternity unit is taken care of by 12 obstetricians-gynaecologists and 21 midwives.

Participants, sampling and follow-up.

The cases were selected based on the guidelines of the Obstetricians and Gynaecologists of Canada [4], the Royal College of Obstetricians and Gynaecologists [6] and the International Federation of Obstetricians and Gynaecology [5]. The minimal sample size was calculated assuming a VBD prevalence rate of 3% [1] and a precision of 5% [14], hence a minimum of 48 cases of VBD required. Each case of VBD of newborn weighing 2500 − 3500g was matched for maternal age and parity to four consecutive VCD of newborns weighing 2500 − 3500g. We excluded all pregnant women with multiple gestations, footling breech presentation, clinically inadequate maternal pelvis, preterm delivery (less than 37 weeks of gestation), post term pregnancies (≥ 41 weeks of gestation), known cases of foetal demise prior to the onset of labour. Additional exclusion criteria were the presence of a major foetal congenital anomaly (like anencephaly, congenital heart diseases, hydrocephalus), or if there was a contraindication to vaginal delivery such as placenta praevia. In both VBD and VCD groups, we excluded cases of vaginal delivery converted to caesarean delivery. In both groups, women and their newborns were followed-up retrospectively till six weeks after

delivery, corresponding to the end of the puerperal period for women and the next vaccination schedule for newborns.

Management of delivery

In this hospital, it is a policy for an experienced obstetrician was present for every VBD and to augment breech labour only with oxytocin. All deliveries occurred with women lying in the recumbent position with legs in holders. Foetal hand monitoring electronically by means of a cardiotocography machine.

Data collection and variables.

- We identified the records of all women-newborn couple for term singleton breech deliveries using the delivery registers. Their medical records were then retrieved from the hospital archives for data extraction. The variables studied were:
- Maternal demographic data: maternal age, marital status and profession.
 - Obstetric history: parity, number of antenatal care visits and follow-up of pregnancy
 - **Details of labour:** foetal presentation, foetal heart rhythm, premature rupture of membranes, umbilical cord prolapse, uterine contractions, colour of amniotic fluid, duration of labour, episiotomy, perineal tears, APGAR score at the 5th minute and birth injuries, perinatal deaths.
 - Follow-up data: the occurrence of postpartum haemorrhage, urinary or faecal incontinence in women, and perinatal mortality for newborns.

Definition of terms

Brachial plexus injury was defined as any paralysis of the muscles of the shoulder girdle, arm, forearm of the newborn and occurring after dystocia (difficult childbirth). It was diagnosed by the attending obstetrician or midewife at birth and confirmed by a paediatrician during the first physical examination of the newborn within 24 hours of birth. Birth asphyxia was diagnosed based on the Modified Sarnat-Sarnat Score [15] and a five-minute Apgar score ≤ 3 associated with neurological signs such as hypotonia, coma or convulsions [16]. The length of labour was the estimated time period from 4 cm cervical dilatation to expulsion of the foetus. For all deliveries, this time interval was monitored and recorded on a partogram. Foetal Distress was defined as the occurrence of foeatal tachycardia (foetal heart beats > 160 beats/min) or foetal bradycardia (< 110 beats/min) [17]. PPH was defined as an estimated blood loss greater than 500 ml within 24 hours after vaginal delivery [18].

Data management and statistical analysis

Data was entered in Epi Info 7.1.3.3 software. Comparison of variables between pregnant women who had VBD and VCD was done using the Chi-square test or Fisher exact test where appropriate. Odds ratios (OR) and their corresponding 95% confidence intervals (95% CI) were calculated in order to measure associations. The original alpha-value was set at 0.05. In order to reduce the chance of obtaining a type 1 error from the multiple analyses performed on the same dependent variable, Bonferroni adjusted p-values were calculated by dividing the alpha-value by the number of comparisons. Hence, any comparison was statistically significant if it was inferior to the Bonferroni adjusted p-value. Variables with too much missing data precluding meaningful analyses were excluded.

Ethical consideration

- The study was approved by the Institutional Review Board of the Faculty of Medicine and
- Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon.

174 Results

Demographic and obstetrical characteristics

During the five-year review period, a total of 13, 695 deliveries were recorded. Among these deliveries, 364 breech deliveries occurred, giving an incidence of 26.6 per 1000 deliveries. After strict application of our eligibility criteria, we retained the files of 53 women with singleton term vaginal breech deliveries of babies weighing between 2500 - 3500g (Figure 1). Of the 53 VBD, 12 (22.6%) were unexpected breech births diagnosed during labour in the delivery room and nine (17%) vaginal breech births required forceps delivery. These women were matched to 212 women with singleton term VCD of newborns weighing between 2500 - 3500g during the same study period. There were 35 frank breech presentations (66%) and complete breech in 18 cases (34%). The maternal ages ranged from 15 to 45 years and the most frequent age group was 20 – 30 years (54.7%). Half had attended at least four antenatal care visits, 54.7% were unemployed and 45.3% were married. Both VBD and VCD groups showed similarities in maternal age, parity, marital and employment status (table 1).

Maternal outcomes

Unlike pregnant women who had VCD, those who underwent VBD were more likely to have emission of meconium stained amniotic fluid (OR: 13.45; 95% CI: 4.54-39.84; p <0.001), prolonged labour (OR: 8.05; 95% CI: 3.00-11.47; p <0.001), premature rupture of

membranes (OR: 2.14; 95% CI: 1.02-4.48; p = 0.0448), and postpartum haemorrhage (OR: 3.07; 95% CI: 1.11-8.50; p = 0.0305). After Bonferroni adjustment (p-value < 0.00556), only prolonged labour, meconium stained amniotic fluid and delivery by a midwife were retained as determinants of adverse maternal outcomes of VBD (table 2).

Neonatal outcomes

Compared to babies born of VCD, those delivered through VBD were more likely to have foetal distress (OR: 2.05; 95% CI: 1.14-3.67; p = 0.0153), brachial plexus injury (OR: 3.91; 95% CI: 2.11-7.26; p = 0.0262), and about five-fold as likely to suffer from birth asphyxia (OR: 4.74; 95% CI: 3.09-7.26; p < 0.001). Only birth asphyxia was retained as an adverse neonatal outcome after Bonferroni correction (p < 0.0125) (table 3).

Discussion

- This study aimed at determining the maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in a tertiary mother and child hospital in the capital city of Cameroon. Despite the application of the aforementioned guidelines [4–6], VBD was found to be significantly associated with prolonged labour (OR: 8.05; 95% CI: 3.00-11.47; p <0.001), emission of meconium stained amniotic fluid (OR: 13.45; 95% CI: 4.54-39.84; p <0.001), and birth asphyxia (OR: 10.24; 95% CI: 4.92-21.31; p <0.001).
- Despite the application of the aforementioned guidelines [4–6], VBD was found to be significantly associated with prolonged labour, meconium stained amniotic fluid and birth asphyxia. Our observation could be the result of the high incidence of dystocia associated with this presentation [19].

The findings in this study indicate that the perinatal mortality in VBD was comparable to that of VCD (2% vs 0%; p=0.2). This may be attributed to the fact that the study was carried out in referral hospital with an experienced obstetric team and with means of electronic foetal monitoring (cardiotocography) to timely detect warning signs during vaginal breech birth. These results are consistent with the studies reporting no difference in the perinatal mortality following breech delivery in resource-limited settings [20,21]. On the other hand, Kemfang et al [22] in a similar study setting in Cameroon reported a significant perinatal mortality (p<0.01) for breech deliveries, which could be due to the absence of well-defined selection criteria for vaginal breech delivery in their series. Their observed perinatal mortality was in cases of macrosomia, nuchal extension, dystocic labour and placental abruption, which were all excluded in the current cohort.

Babies born through VBD were more likely to have birth asphyxia than those who had a vaginal cephalic birth (47% vs. 8%; p < 0.001), corroborating previous studies from both high-income [3,23] and low-income settings [20,21,24]. This could be related to the fact that breech foetuses face an increased risk of hypoxic-anoxic events from head entrapment, rapid decompression of the head, and other birth trauma [7].

The main limitation of this study is its retrospective nature of data collection, which was subject to a potential risk of incorrectly completed records. Also, the study was conducted in an urban centre with standards of a tertiary level of care, which implies cautious generalization of our results to health facilities not having the same level of care in rural settings. Nevertheless, based on careful selection criteria of singleton term VBD and a robust statistical analysis to eliminate bias, we reviewed a five-year period to assess the outcomes of VBD in a low-income country where caesarean delivery cannot be generalized as the route of delivery for all breech presentations because of its financial cost and the prevalent inadequate

surgical infrastructure in most health facilities. Our finding is a significant contribution to the on-going debate on the safety of vaginal breech delivery in sub-Saharan Africa.

Conclusion

Our findings suggest when breech delivery guidelines are applied, VBD of singleton term pregnancies is still associated with a three-fold risk of prolonged labour, a four-fold risk of meconium stained amniotic fluid, and a five-fold risk of birth asphyxia. This finding does not discount the role of VBD in resource-poor settings, but we emphasize the need for specific precautions like close monitoring of labour and adequate anticipation for neonatal resuscitation in order to reduce these complications. Also, elective caesarean section should be performed for singleton breech term pregnancies whenever possible. This would need to be further explored in large multicentre clinical trials in our resource-constrained settings.

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Authors' contributions: JSD, PF and EM: Study conception and design, acquisition of data, data analysis and interpretation, manuscript writing and critical revisions. FM: Study conception and design, acquisition of data, data analysis and interpretation and manuscript writing. JNT, MNT, RT and VA: Acquisition of data, data analysis and interpretation, manuscript writing and revisions. All authors read and approved the final manuscript.

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258	Competing interests: We have read and understood BMJ policy on declaration of interests
259	and declare that we have no competing interests.

- **Ethical Approval:** The study was approved by the Institutional Review Board of the Faculty
- of Medicine and Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon.
- **Data sharing statement:** No additional data are available.

Figure and Table Legend

- Figure 1: Flow chart depicting selection of vaginal breech delivery cases.
- Table 1: Socio-demographic characteristics and obstetric history of mothers
- Table 2: Maternal outcomes of vaginal breech delivery
- Table 3: Analysis of neonatal outcomes associated with vaginal breech delivery

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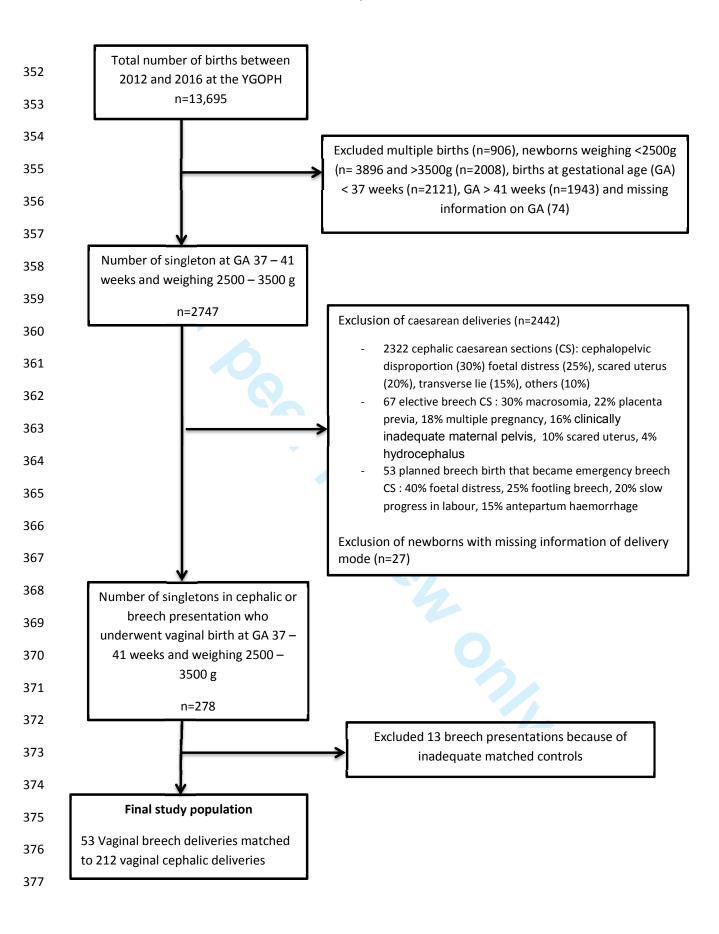


Table 1: Socio-demographic characteristics and obstetric history of mothers

Number (%)	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	p-value
31 (11.7%)	6	25	0.3068
145(54.7%)	25	120	
85(32.1%)	20	65	
4 (1.5%)	2	2	
•			
145 (54.7%)	31	114	0.3323
` /	10	62	
1	11		
, ,			
120 (45.3%)	28	96	0.4414
			0
` /			
27 (10.270)	O	22	
104 (39 3%)	18	86	0.6199
			0.01
101 (36.170)	23	76	
125 (510/)	17	115	0.0293
			0.0293
127 (48%)	8	19	
	31 (11.7%) 145(54.7%) 85(32.1%)	breech delivery (n=53) 31 (11.7%) 6 145(54.7%) 25 85(32.1%) 20 4 (1.5%) 2 145 (54.7%) 31 72 (27.2%) 10 47 (18.1%) 11 120 (45.3%) 28 117 (44.2%) 18 27 (10.2%) 6 104 (39.3%) 18 60 (22.6%) 12 101 (38.1%) 23	breech delivery (n=53) cephalic delivery (n=212) 31 (11.7%) 6 25 145(54.7%) 25 120 85(32.1%) 20 65 4 (1.5%) 2 2 145 (54.7%) 31 114 72 (27.2%) 10 62 47 (18.1%) 11 36 120 (45.3%) 28 96 117 (44.2%) 18 94 27 (10.2%) 6 22 104 (39.3%) 18 86 60 (22.6%) 12 48 101 (38.1%) 23 78 135 (51%) 17 115

391 Table 2: Maternal outcomes of vaginal breech delivery

Variables	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	Odds ratio	95% confidenc e interval	p-value
Premature rupture of					
membranes					
Yes	13 (24.5%)	28 (13%)	2.14	1.02-4.48	0.0448
No	40 (75.5%)	184 (87%)			
Meconium stained amniotic fluid					
Yes	13 (24.5%)	5 (2.4%)	13.45	4.54-39.84	< 0.001
No	40 (75.5%)	207 (97.6)			
Umbilical cord prolapse					
Yes	2 (4%)	1 (0.5%)	8.27	0.74-93.05	0.087
No	51 (96%)	211 (99.5%)			
Prolonged labour (> 12 hours)					
Yes	25 (47%)	28 (13%)	8.05	3.00-11.47	< 0.001
No	28 (53%)	184 (87%)			
Course of labour					
Augmented with oxytocin	2 (4%)	15 (7.1%)	0.52	0.11-2.33	0.3882
Spontaneous	51 (96%)	197 (92.9%)			
Episiotomies					
Yes	3 (5.7%)	22 (10.4%)	0.52	0.15-1.80	0.301
No	50 (94.3%)	190 (89.6%)			
Perineal tears					
Yes	17 (32%)	64 (30%)	1.09	0.57-2.09	0.7897
No	36 (68%)	148 (70%)			
Uterine atony					
Yes	1 (2%)	5 (2.4%)	0.79	0.09-6.96	0.8368
No	52 (98%)	207 (97.6%)			
Postpartum haemorrhage					
Yes	7 (13.2%)	10 (4.7%)	3.07	1.11-8.50	0.0305
No	46 (86.8%)	202 (95.3%)			

Bonferroni corrected p-value < 0.00556.

Table 3: Analysis of neonatal outcomes associated with vaginal breech delivery

Foetal distress Yes 9 (17%) 15 (7%) 2.69 1.11-6.53 0.0293 No 44 (83%) 197 (93%) Neonatal asphyxia Yes 25 (47.2%) 17 (8.0%) 10.24 4.92-21.31 < 0.001 No 28 (52.8%) 195 (92%) Brachial plexus injury Yes 3 (5.7%) 01(0.5%) 12.66 1.28-124.28 0.0262 No 50 (94.3%) 211 (99.5%) Perinatal deaths Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.	Neonatal outcomes	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	Odds Ratio	95% confidence interval	p-value
No 44 (83%) 197 (93%) Neonatal asphyxia Yes 25 (47.2%) 17 (8.0%) 10.24 4.92-21.31 < 0.001 No 28 (52.8%) 195 (92%) Brachial plexus injury Yes 3 (5.7%) 01(0.5%) 12.66 1.28-124.28 0.0262 No 50 (94.3%) 211 (99.5%) Perinatal deaths Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.	Foetal distress	(== ==)	()			
No 44 (83%) 197 (93%) Neonatal asphyxia Yes 25 (47.2%) 17 (8.0%) 10.24 4.92-21.31 < 0.001 No 28 (52.8%) 195 (92%) Brachial plexus injury Yes 3 (5.7%) 01(0.5%) 12.66 1.28-124.28 0.0262 No 50 (94.3%) 211 (99.5%) Perinatal deaths Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.	Yes	9 (17%)	15 (7%)	2.69	1.11-6.53	0.0293
Neonatal asphyxia Yes 25 (47.2%) 17 (8.0%) 10.24 4.92-21.31 < 0.001 No 28 (52.8%) 195 (92%) Brachial plexus injury Yes 3 (5.7%) 01(0.5%) 12.66 1.28-124.28 0.0262 No 50 (94.3%) 211 (99.5%) Perinatal deaths Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.	No					
Yes	Neonatal asphyxia	` ,	`			
Brachial plexus injury Yes 3 (5.7%) 01(0.5%) 12.66 1.28-124.28 0.0262 No 50 (94.3%) 211 (99.5%) Perinatal deaths Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.		25 (47.2%)	17 (8.0%)	10.24	4.92-21.31	< 0.001
Yes 3 (5.7%) 01(0.5%) 12.66 1.28-124.28 0.0262 No 50 (94.3%) 211 (99.5%) Perinatal deaths Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.	No	28 (52.8%)	195 (92%)			
Yes 3 (5.7%) 01(0.5%) 12.66 1.28-124.28 0.0262 No 50 (94.3%) 211 (99.5%) Perinatal deaths Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.	Brachial plexus injury					
Perinatal deaths Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.		3 (5.7%)	01(0.5%)	12.66	1.28-124.28	0.0262
Yes 1 (2%) 00 12.14 0.49-302.36 0.128 No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.		50 (94.3%)	211 (99.5%)			
No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.	Perinatal deaths					
No 52 (98%) 212 (100%) Bonferroni corrected p-value < 0.0125.	Yes			12.14	0.49-302.36	0.128
		52 (98%)	212 (100%)			

Bonferroni corrected p-value < 0.0125.

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 3 and 4
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4
Methods			
Study design	4	Present key elements of study design early in the paper	Page 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pages 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Page 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6
Bias	9	Describe any efforts to address potential sources of bias	Page 6
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 6
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	Page 6
		(d) If applicable, explain how loss to follow-up was addressed	Page 6
		(e) Describe any sensitivity analyses	-
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed	Page 7 and 13
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	Page 7 and 13
		(c) Consider use of a flow diagram	Page 13
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 7 and 14
		(b) Indicate number of participants with missing data for each variable of interest	Page 7 and 13
		(c) Summarise follow-up time (eg, average and total amount)	Page 7
Outcome data	15*	Report numbers of outcome events or summary measures over time	Pages 7 and 8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	Pages 7, 8, 15 and 16
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 8
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	Pages 9 and 10
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	Not applicable
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in a carefully selected Cameroonian population: a cohort study.

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- 1 Title:
- 2 Maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in
- a carefully selected Cameroonian population: a cohort study.
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24 Abstract

- **Background and objectives:** Vaginal breech delivery (VBD) is known to be associated with
- 26 more perinatal and maternal complications. Very few studies on the subject have been carried
- out in poor resource settings. The aim of this study was to determine maternal and neonatal
- outcomes in carefully selected cases of VBD for singleton term pregnancies in a tertiary
- 29 centre in Cameroon.
- **Design:** A retrospective cohort study
- **Setting:** A tertiary hospital in Yaounde, Cameroon
- Participants: Cases of VBD of newborns weighing 2500 3500g were matched in a ratio of
- 33 1:4 to consecutive vaginal cephalic deliveries (VCD) of newborns weighing 2500 3500g
- over a five-year period. Both groups were matched for maternal age and parity. We excluded
- 35 cases of multiple gestations, footling breech, clinically inadequate maternal pelvis, preterm
- delivery, post term pregnancies, foetal demise prior to the onset of labour, placenta praevia
- and foetal anomaly incompatible with vaginal delivery.
- 38 Outcome measures: Neonatal and maternal adverse outcomes of VBD observed till six
- 39 weeks after delivery analysed using Bonferroni correction.
- 40 Results: Fifty-three (53) VBD were matched against 212 VCD. Unlike women who had
- VCD, those who underwent VBD were more likely to have prolonged labour (OR: 8.05; 95%
- 42 CI: 3.00-11.47; p <0.001), and their newborns were more likely to suffer from birth asphyxia
- 43 (OR: 10.24; 95% CI: 4.92-21.31; p <0.001).
- 44 Conclusion: The study infers a strong association between VBD of singleton term
- 45 pregnancies and maternofoetal morbidity when specific protocols are applied. This however,
- 46 failed to translate into higher differences in perinatal mortality. This finding does not discount
- 47 the role of VBD in low-income countries, but we emphasize the need for specific precautions
- 48 like close monitoring of labour and adequate anticipation for neonatal resuscitation in order
- 49 to reduce these complications.
- **Keywords:** breech, vaginal delivery, cephalic presentation, singleton term pregnancies,
- 51 outcome, Cameroon.

Strengths of the study:

- The use of guidelines to select cases of vaginal breech delivery in order to decrease the risk of selection bias in the findings obtained.
- Bias was further reduced by calculating Bonferroni adjusted p-values

Limitations of the study:

- The study had a retrospective nature of data collection, which was subject to a
 potential risk of incorrectly completed records.
- The study was carried out in a single centre with standards of a tertiary level of care, which implies cautious generalization of results to health facilities not having the same level of care.

Introduction:

- Breech presentations represent 3 4% of all foetal presentations at term (1). Vaginal breech deliveries (VBD) are associated with a ten-fold increase in perinatal mortality when compared to vaginal cephalic deliveries (VCD) (2).
 - The safest mode of delivery in case of breech presentation has long been a debate in obstetrics (3). It is recommended to carry out elective caesarean section rather than vaginal delivery for singleton term breech pregnancies when there is foetal distress, macrosomia, footling breech presentation, clinically inadequate maternal pelvis, growth-restricted baby, placenta praevia or foetal anomaly incompatible with vaginal delivery, or if an experienced clinician is absent or the clinician lacks adequate expertise for VBD (4–6). Evidence abounds that unlike VBD for singleton term pregnancies, elective caesarean section reduces perinatal mortality and morbidity, as well as maternal morbidity (urinary incontinence and postpartum perineal pains) in developed countries (7). However, in resource-limited countries, the outcomes of both VBD and elective caesarean breech delivery appear comparable (7), possibly due to the prevailing expertise of birth attendants in VBD in these resource-

challenged settings (3). Furthermore, it has been shown that as much as 39 caesarean sections are required to prevent one neonatal death or adverse neonatal outcome in low-income countries compared to seven caesarean sections needed in high-income settings (3). Hence, a health policy generalizing the indication of caesarean section to all breech presentations in low-income countries would require significant additional investments in their health care systems. Also, the presence of a scarred uterus puts subsequent pregnancies at increased risk of complications such as placenta praevia, placenta accreta and placenta abruption, uterine rupture, repeat caesarean section and repeat breech presentation (6,8–11). Likewise, elective caesarean section for breech presentation cannot be performed in all resource-limited settings due to its financial cost and the prevalent inadequate surgical infrastructure in most health facilities (7).

As such, external cephalic version for singleton term pregnancies has been recommended as a safe and cost-effective means to revert breech to cephalic presentation and avert the resort to either VBD or caesarean sections (12). However, external cephalic version is not routinely performed in clinical practice because many health personnel lack its mastery or unduly perceive it to be associated with adverse perinatal outcomes (13). Thus, vaginal delivery is still the main route of delivery in resource-limited environments. Data on vaginal breech delivery for singleton term pregnancies in sub-Saharan Africa is scarce, thus, explaining the lack of consensus on the management of this foetal presentation in the continent. The aim of this study was to investigate the maternal and neonatal outcomes of vaginal delivery of singleton term foetus in breech presentation following strict selection criteria in a tertiary centre of Cameroon.

Materials and Methods

Study design and setting

In this cohort study, we retrospectively reviewed case notes of all pregnant women at term who had a VBD and pregnant women at term with VCD at the maternity of the Yaounde Gynaeco-Obstetric and Pediatric Hospital (YGOPH) between 1st January 2012 to 31st December 2016. The YGOPH is a tertiary hospital located in Yaoundé, the political capital of Cameroon. This health facility serves as a major referral centre for mother and child care in Yaounde and its environs. Its annual number of child births varies between 2000 to 2500 deliveries. The YGOPH is equipped with modern equipment and personnel to provide comprehensive Emergency Obstetric and Neonatal Care (EmONC) services. The maternity unit is taken care of by 12 obstetricians-gynaecologists and 21 midwives. The hospital has a neonatology unit is taken care of by five paediatricians, two general practitioners, and forteen nurses.

Participants, sampling and follow-up.

The cases were selected based on the guidelines of the Obstetricians and Gynaecologists of Canada (4), the International Federation of Obstetricians and Gynaecology (5) and the Royal College of Obstetricians and Gynaecologists (6). The minimal sample size was calculated assuming a VBD prevalence rate of 3% (1) and a precision of 5% (14), hence a minimum of 48 cases of VBD required. Each case of VBD of newborn weighing 2500 − 3500g was matched for maternal age and parity to four consecutive VCD of newborns weighing 2500 − 3500g. We excluded all pregnant women with multiple gestations, footling breech presentation, clinically inadequate maternal pelvis, preterm delivery (less than 37 weeks of gestation), post term pregnancies (≥ 41 weeks of gestation), known cases of foetal demise prior to the onset of labour. Additional exclusion criteria were the presence of a major foetal

congenital anomaly (like anencephaly, congenital heart diseases, hydrocephalus), or if there was a contraindication to vaginal delivery such as placenta praevia. In both VBD and VCD groups, we excluded cases of vaginal delivery converted to caesarean delivery. Data was retrieved from case files on important variables in both groups for women and their newborns.

Management of delivery

In this hospital, it is a policy for an experienced obstetrician to be present for every VBD and to augment breech labour only with oxytocin in cases of dynamic dystocia. All deliveries occurred with women lying in the recumbent position with legs in holders. Foetal heart monitoring during labour is done electronically by means of a cardiotocography machine.

Data collection and variables.

- We identified the records of all women-newborn couples for term singleton breech deliveries using the delivery registers. Their medical records were then retrieved from the hospital archives for data extraction. The variables studied were:
 - Maternal demographic data: maternal age, marital status and profession.
- **Obstetric history:** parity and number of antenatal care visits.
 - Details of labour: foetal presentation, foetal heart rhythm, premature rupture of membranes, umbilical cord prolapse, uterine contractions, colour of amniotic fluid, duration of labour, episiotomy, perineal tears, APGAR score at the 5th minute and birth injuries, perinatal deaths.
 - Postpartum complications: postpartum haemorrhage, urinary or faecal incontinence in women, and perinatal mortality for newborns.

Definition of terms

Brachial plexus injury was defined as any paralysis of the muscles of the shoulder girdle, arm, forearm of the newborn and occurring after dystocia (difficult childbirth). It was diagnosed by the attending obstetrician or midewife at birth and confirmed by a paediatrician during the first physical examination of the newborn within 24 hours of birth. Birth asphyxia was diagnosed based on the Modified Sarnat-Sarnat Score (15) and a five-minute Apgar score ≤ 3 associated with neurological signs such as hypotonia, coma or convulsions (16). The length of labour was the estimated time period from 4 cm cervical dilatation to expulsion of the foetus. For all deliveries, this time interval was monitored and recorded on a partogram. Foetal Distress was defined as the occurrence of foeatal tachycardia (foetal heart beats ≥ 160 beats/min) or foetal bradycardia (≤ 110 beats/min) (17). PPH was defined as an estimated blood loss greater than 500 ml within 24 hours after vaginal delivery (18).

Data management and statistical analysis

Data was entered in Epi Info 7.1.3.3 software. Comparison of variables between pregnant women who had VBD and VCD was done using the Chi-square test or Fisher exact test where appropriate. Odds ratios (OR) and their corresponding 95% confidence intervals (95% CI) were calculated in order to measure associations. The original alpha-value was set at 0.05. In order to reduce the chance of obtaining a type 1 error from the multiple analyses performed on the same dependent variable, Bonferroni adjusted p-values were calculated by dividing the alpha-value by the number of comparisons. Hence, any comparison was statistically significant if it was inferior to the Bonferroni adjusted p-value.

Ethical consideration

- The study was approved by the Institutional Review Board of the Faculty of Medicine and
- Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon.

175 Results

Demographic and obstetrical characteristics

During the five-year review period, a total of 13, 695 deliveries were recorded. Among these deliveries, 364 breech deliveries occurred, giving an incidence of 26.6 per 1000 deliveries. After strict application of our eligibility criteria, we retained the files of 53 women with singleton term vaginal breech deliveries of babies weighing between 2500 - 3500g (Figure 1). Of the 53 VBD, 12 (22.6%) were unexpected breech births diagnosed during labour and nine (17%) vaginal breech births required forceps delivery. These women were matched to 212 women with singleton term VCD of newborns weighing between 2500 - 3500g during the same study period. There were 35 frank breech presentations (66%) and complete breech in 18 cases (34%). The maternal ages ranged from 15 to 45 years and the most frequent age group was 20 – 30 years (54.7%). Half had attended at least four antenatal care (ANC) visits, 54.7% were unemployed and 45.3% were married. Both VBD and VCD groups showed similarities in maternal age, parity, marital and employment status (table 1).

Maternal outcomes

Unlike pregnant women who had VCD, those who underwent VBD were more likely to have emission of meconium stained amniotic fluid (OR: 13.45; 95% CI: 4.54-39.84; p <0.001), prolonged labour (OR: 8.05; 95% CI: 3.00-11.47; p <0.001), premature rupture of

193	membranes (OR: 2.14 ; 95% CI: $1.02-4.48$; $p = 0.04$), and postpartum haemorrhage (OR:
194	3.07; 95% CI: 1.11-8.50; p = 0.03). After Bonferroni adjustment (p-value < 0.005), only
195	prolonged labour, meconium stained amniotic fluid and delivery by a midwife were retained
196	as determinants of adverse maternal outcomes of VBD (table 2).

Neonatal outcomes

Compared to babies born of VCD, those delivered through VBD were more likely to have foetal distress (OR: 2.05; 95% CI: 1.14-3.67; p = 0.0153), brachial plexus injury (OR: 3.91; 95% CI: 2.11-7.26; p = 0.0262), and about five-fold as likely to suffer from birth asphyxia (OR: 4.74; 95% CI: 3.09-7.26; p < 0.001). Only birth asphyxia was retained as an adverse neonatal outcome after Bonferroni correction (p < 0.0125) (table 3).

Discussion

This study aimed at determining the maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in a tertiary mother and child hospital in Yaounde, Cameroon. Despite the application of the aforementioned guidelines (4–6), VBD was found to be significantly associated with prolonged labour (OR: 8.05; 95% CI: 3.00-11.47; p <0.001), emission of meconium stained amniotic fluid (OR: 13.45; 95% CI: 4.54-39.84; p <0.001), and birth asphyxia (OR: 10.24; 95% CI: 4.92-21.31; p <0.001). This observation could be the result of the high incidence of dystocia associated with this presentation (19).

The findings indicate that the perinatal mortality in VBD was comparable to that of VCD (2% vs 0%; p=0.2). This may be attributed to the fact that the study was carried out in referral hospital with an experienced obstetric team and with means of electronic foetal

monitoring (cardiotocography) to timely detect warning signs of non-reassuring foetal status during vaginal breech birth. These results are consistent with the studies reporting no difference in the perinatal mortality following breech delivery in resource-limited settings (20,21). On the other hand, Kemfang et al (22) in a similar study setting in Cameroon reported a significant perinatal mortality (p<0.01) for breech deliveries, which could be due to the absence of well-defined selection criteria for vaginal breech delivery in their series. Their observed perinatal mortality was in cases of macrosomia, nuchal extension, dystocic labour and placental abruption, which were all excluded in the current cohort.

Neonates delivered through breech birth were more likely to have birth asphyxia than those who had a vaginal cephalic birth (47% vs. 8%; p < 0.001), corroborating previous studies from both high-income (3,23) and low-income settings (20,21,24). This could be related to the fact that breech foetuses face an increased risk of hypoxic-anoxic events from head entrapment, rapid decompression of the head, and other birth trauma (7).

The main limitation of this study was that being a retrospective study, data collection was subject to the potential risk of reviewing incorrectly completed records. Furthermore, less than four ANC visits were attended in 68% of VBD compared to 43% of VCD studied (p = 0.002). ANC attendance was not a matching variable between the VBD and VCD groups. Hence, the VBD cases were a higher risk group from the onset of the study and 22.6% of VBD were unrecognised before the onset of labour. Also, the study was conducted in an urban centre with standards of a tertiary level of care, which implies cautious generalization of our results to health facilities not having the same level of care. Nevertheless, based on careful selection criteria of singleton term VBD and the statistical analysis used to eliminate bias, we reviewed a five-year period to assess the outcomes of VBD in a low-income country where caesarean delivery cannot be generalized as the route of delivery for all breech

presentations because of its financial cost and the prevalent inadequate surgical infrastructure in most health facilities. The findings are a significant contribution to the on-going debate on the safety of vaginal breech delivery in sub-Saharan Africa.

Conclusion

The findings suggest that even when breech delivery guidelines are applied, VBD of singleton term pregnancies is still associated with a high incidence of maternal and perinatal morbidity. This finding does not discount the role of VBD in resource-poor settings, but emphasises the need for rigorous monitoring of labour, timely decision and adequate anticipation for neonatal resuscitation in order to reduce these complications. Also, the practise of external cephalic version should be taught and promoted in this resource-limited setting as a means to convert breech to cephalic presentations and reduce the perinatal and maternal morbidities associated with VBD. Refresher courses for the management of breech birth should be organised for health personnel in order to minimize risk of brachial plexus injury. Based on the limitations of the study, there is a need to carry out large multicentre clinical trials in our resource-limited settings.

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Authors' contributions: JSD, PF and EM: Study conception and design, acquisition of data, data analysis and interpretation, manuscript writing and critical revisions. FM: Study conception and design, acquisition of data, data analysis and interpretation and manuscript

- writing. JNT, MNT, RT and VA: Acquisition of data, data analysis and interpretation, manuscript writing and revisions. All authors read and approved the final manuscript. Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors Competing interests: We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests. Ethical Approval: The study was approved by the Institutional Review Board of the Faculty of Medicine and Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon. **Data sharing statement:** No additional data are available. Figure and Table Legend Figure 1: Flow chart depicting selection of vaginal breech and cephalic delivery cases. Table 1: Socio-demographic characteristics and obstetric history of mothers

- Table 2: Maternal outcomes of vaginal breech delivery
- Table 3: Analysis of neonatal outcomes associated with vaginal breech delivery

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Table 1: Socio-demographic characteristics and obstetric history of mothers

Groups	Number (%)	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	p-value
Maternal age groups (years)				
< 20	31 (11.7%)	6	25	0.3068
20 - 30	145(54.7%)	25	120	
30 - 40	85(32.1%)	20	65	
>40	4 (1.5%)	2	2	
Occupation*				
Unemployed	145 (54.7%)	31	114	0.3323
Employed	72 (27.2%)	10	62	
Self-employed	47 (18.1%)	11	36	
Marital status*				
Married	120 (45.3%)	28	96	0.4414
Single	117 (44.2%)	18	94	
Cohabitation	27 (10.2%)	6	22	
Parity	,			
Nulliparous (parity = 0)	104 (39.3%)	18	86	0.6199
Primiparous (parity = 1)	60 (22.6%)	12	48	
Multiparous (parity > 1)	101 (38.1%)	23	78	
Number of antenatal care visits $^{\beta}$				
≥ 4	135 (51%)	17	115	0.002
_ < 4	127 (48%)	36	91	
^β 1 missing data; ^β 3 missing data				

^{*1} missing data; ^β 3 missing data

Table 2: Maternal outcomes of vaginal breech delivery

Variables	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	Odds ratio	95% confidenc e interval	p-value
D					
Premature rupture of membranes					
	12 (24 50/)	20 (120/)	2 14	1 02 4 40	0.0440
Yes No	13 (24.5%)	28 (13%)	2.14	1.02-4.48	0.0448
	40 (75.5%)	184 (87%)			
Meconium stained amniotic					
fluid	12 (24 50/)	5 (2 40/)	12 45	4.54.20.94	< 0.001
Yes No	13 (24.5%)	5 (2.4%)	13.45	4.54-39.84	< 0.001
	40 (75.5%)	207 (97.6)			
Umbilical cord prolapse	2 (40/)	1 (0.50/)	0.27	0.74.02.05	0.007
Yes	2 (4%)	1 (0.5%)	8.27	0.74-93.05	0.087
No	51 (96%)	211 (99.5%)			
Prolonged labour (> 12					
hours)	25 (470/)	20 (120/)	0.05	2.00.11.47	< 0.001
Yes No	25 (47%)	28 (13%)	8.05	3.00-11.47	< 0.001
	28 (53%)	184 (87%)			
Course of labour	2 (40/)	15 (7 10/)	0.53	0 11 2 22	0.2002
Augmented with oxytocin	2 (4%)	15 (7.1%)	0.52	0.11-2.33	0.3882
Spontaneous	51 (96%)	197 (92.9%)			
Episiotomies	2 (5 70()	22 (10 40/)	0.50	0.15.1.00	0.201
Yes	3 (5.7%)	22 (10.4%)	0.52	0.15-1.80	0.301
No	50 (94.3%)	190 (89.6%)			
Perineal tears	17 (220/)	(4 (200()	1.00	0.57.2.00	0.7007
Yes	17 (32%)	64 (30%)	1.09	0.57-2.09	0.7897
No	36 (68%)	148 (70%)			
Uterine atony	1 (00/)	5 (0 10()	0.70	0.00.606	0.02.60
Yes	1 (2%)	5 (2.4%)	0.79	0.09-6.96	0.8368
No	52 (98%)	207 (97.6%)			
Postpartum haemorrhage	T (10.00()	10 (4 50()	2.05	1 11 0 70	0.0207
Yes	7 (13.2%)	10 (4.7%)	3.07	1.11-8.50	0.0305
No	46 (86.8%)	202 (95.3%)			

Bonferroni corrected p-value < 0.00556.

Table 3: Analysis of neonatal outcomes associated with vaginal breech delivery

Neonatal outcomes	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	Odds Ratio	95% confidence interval	p-value
Foetal distress	(11 00)	(11 212)			
Yes	9 (17%)	15 (7%)	2.69	1.11-6.53	0.0293
No	44 (83%)	197 (93%)			
Neonatal asphyxia	()	()			
Yes	25 (47.2%)	17 (8.0%)	10.24	4.92-21.31	< 0.001
No	28 (52.8%)	195 (92%)			
Brachial plexus injury	,	,			
Yes	3 (5.7%)	01(0.5%)	12.66	1.28-124.28	0.0262
No	50 (94.3%)	211 (99.5%)			
Perinatal deaths		(******)			
Yes	1 (2%)	00	12.14	0.49-302.36	0.128
No	52 (98%)	212 (100%)			*****

Bonferroni corrected p-value < 0.0125.

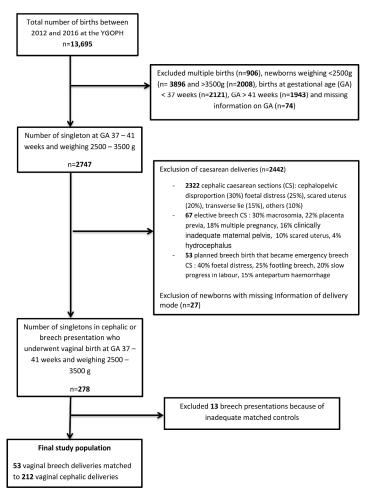


Figure 1: Flow chart depicting selection of vaginal breech and cephalic delivery cases.

Figure 1: Flow chart depicting selection of vaginal breech and cephalic delivery cases.

148x210mm (600 x 600 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 3 and 4
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4
Methods			
Study design	4	Present key elements of study design early in the paper	Page 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pages 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Page 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6
Bias	9	Describe any efforts to address potential sources of bias	Page 6
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 7
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	Page 7
		(d) If applicable, explain how loss to follow-up was addressed	Page 7
		(e) Describe any sensitivity analyses	-
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed	Page 8
·		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	Page 8
		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	Page 8
		(c) Summarise follow-up time (eg, average and total amount)	Page 8
Outcome data	15*	Report numbers of outcome events or summary measures over time	Pages 8 and 9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	Pages 8 and 9
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 9
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	Pages 9 and 10
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	Not applicable
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in a carefully selected Cameroonian population: a cohort study.

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Secondary Subject Heading:	Reproductive medicine
Keywords:	breech, vaginal delivery, cephalic presentation, singleton term pregnancies, outcome, Cameroon



- 1 Title:
- 2 Maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in
- a carefully selected Cameroonian population: a cohort study.
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24 Abstract

- **Background and objectives:** Vaginal breech delivery (VBD) is known to be associated with
- 26 more perinatal and maternal complications. Very few studies on the subject have been carried
- out in poor resource settings. The aim of this study was to determine maternal and neonatal
- outcomes in carefully selected cases of VBD for singleton term pregnancies in a tertiary
- 29 centre in Cameroon.
- **Design:** A retrospective cohort study
- **Setting:** A tertiary hospital in Yaounde, Cameroon
- Participants: Cases of VBD of newborns weighing 2500 3500g were matched in a ratio of
- 33 1:4 to consecutive vaginal cephalic deliveries (VCD) of newborns weighing 2500 3500g
- over a five-year period. Both groups were matched for maternal age and parity. We excluded
- 35 cases of multiple gestations, footling breech, clinically inadequate maternal pelvis, preterm
- delivery, post term pregnancies, foetal demise prior to the onset of labour, placenta praevia
- and foetal anomaly incompatible with vaginal delivery.
- 38 Outcome measures: Neonatal and maternal adverse outcomes of VBD observed till six
- 39 weeks after delivery analysed using Bonferroni correction.
- 40 Results: Fifty-three (53) VBD were matched against 212 VCD. Unlike women who had
- VCD, those who underwent VBD were more likely to have prolonged labour (OR: 8.05; 95%
- 42 CI: 3.00-11.47; p <0.001), and their newborns were more likely to suffer from birth asphyxia
- 43 (OR: 10.24; 95% CI: 4.92-21.31; p <0.001).
- 44 Conclusion: The study infers a strong association between VBD of singleton term
- 45 pregnancies and maternofoetal morbidity when specific protocols are applied. This however,
- 46 failed to translate into higher differences in perinatal mortality. This finding does not discount
- 47 the role of VBD in low-income countries, but we emphasize the need for specific precautions
- 48 like close monitoring of labour and adequate anticipation for neonatal resuscitation in order
- 49 to reduce these complications.
- **Keywords:** breech, vaginal delivery, cephalic presentation, singleton term pregnancies,
- 51 outcome, Cameroon.

Strengths of the study:

- The use of guidelines to select cases of vaginal breech delivery in order to decrease the risk of selection bias in the findings obtained.
- Bias was further reduced by calculating Bonferroni adjusted p-values

Limitations of the study:

- The study had a retrospective nature of data collection, which was subject to a
 potential risk of incorrectly completed records.
- The study was carried out in a single centre with standards of a tertiary level of care, which implies cautious generalization of results to health facilities not having the same level of care.

Introduction:

- Breech presentations represent 3 4% of all foetal presentations at term (1). Vaginal breech deliveries (VBD) are associated with a ten-fold increase in perinatal mortality when compared to vaginal cephalic deliveries (VCD) (2).
 - The safest mode of delivery in case of breech presentation has long been a debate in obstetrics (3). It is recommended to carry out elective caesarean section rather than vaginal delivery for singleton term breech pregnancies when there is foetal distress, macrosomia, footling breech presentation, clinically inadequate maternal pelvis, growth-restricted baby, placenta praevia or foetal anomaly incompatible with vaginal delivery, or if an experienced clinician is absent or the clinician lacks adequate expertise for VBD (4–6). Evidence abounds that unlike VBD for singleton term pregnancies, elective caesarean section reduces perinatal mortality and morbidity, as well as maternal morbidity (urinary incontinence and postpartum perineal pains) in developed countries (7). However, in resource-limited countries, the outcomes of both VBD and elective caesarean breech delivery appear comparable (7), possibly due to the prevailing expertise of birth attendants in VBD in these resource-

challenged settings (3). Furthermore, it has been shown that as much as 39 caesarean sections are required to prevent one neonatal death or adverse neonatal outcome in low-income countries compared to seven caesarean sections needed in high-income settings (3). Hence, a health policy generalizing the indication of caesarean section to all breech presentations in low-income countries would require significant additional investments in their health care systems. Also, the presence of a scarred uterus puts subsequent pregnancies at increased risk of complications such as placenta praevia, placenta accreta and placenta abruption, uterine rupture, repeat caesarean section and repeat breech presentation (6,8–11). Likewise, elective caesarean section for breech presentation cannot be performed in all resource-limited settings due to its financial cost and the prevalent inadequate surgical infrastructure in most health facilities (7).

As such, external cephalic version for singleton term pregnancies has been recommended as a safe and cost-effective means to revert breech to cephalic presentation and avert the resort to either VBD or caesarean sections (12). However, external cephalic version is not routinely performed in clinical practice because many health personnel lack its mastery or unduly perceive it to be associated with adverse perinatal outcomes (13). Thus, vaginal delivery is still the main route of delivery in resource-limited environments. Data on vaginal breech delivery for singleton term pregnancies in sub-Saharan Africa is scarce, thus, explaining the lack of consensus on the management of this foetal presentation in the continent. The aim of this study was to elucidate the maternal and neonatal outcomes of vaginal delivery of singleton term foetus in breech presentation following strict selection criteria in a tertiary centre of Cameroon.

Materials and Methods

Study design and setting

In this cohort study, we reviewed case notes of all pregnant women at term who had a VBD and pregnant women at term with VCD at the maternity of the Yaounde Gynaeco-Obstetric and Pediatric Hospital (YGOPH) between 1st January 2012 to 31st December 2016. The YGOPH is a tertiary hospital located in Yaoundé, the political capital of Cameroon. This health facility serves as a major referral centre for mother and child care in Yaounde and its environs. Its annual number of child births varies between 2000 to 2500 deliveries. The YGOPH is equipped with modern equipment and personnel to provide comprehensive Emergency Obstetric and Neonatal Care (EmONC) services. The maternity unit is managed by 12 obstetricians-gynaecologists and 21 midwives. The hospital has a neonatology unit whose staff is comprised of five paediatricians, two general practitioners, and fourteen nurses.

Participants, sampling and follow-up.

The cases were selected based on the guidelines of the Obstetricians and Gynaecologists of Canada (4), the International Federation of Obstetricians and Gynaecology (5) and the Royal College of Obstetricians and Gynaecologists (6). Using a ratio of control to cases of 4, a 95% confidence interval, minimum power to detect a difference of 80%, and assuming a minimum odd ratio of 2 for differences to be detected, the formula for difference in proportions (14) was used to calculate the minimum sample size. Therefore the number of VBD required for the study was 41 and the number of controls (VCD) was 164. Each case of VBD of newborn weighing 2500 – 3500g was matched for maternal age and parity to four consecutive VCD of newborns weighing 2500 – 3500g. We excluded all pregnant women with multiple gestations, footling breech presentation, clinically inadequate maternal pelvis,

preterm delivery (less than 37 weeks of gestation), post term pregnancies (≥ 41 weeks of gestation), known cases of foetal demise prior to the onset of labour. Additional exclusion criteria were the presence of a major foetal congenital anomaly (like anencephaly, congenital heart diseases, hydrocephalus), or if there was a contraindication to vaginal delivery such as placenta praevia. In both VBD and VCD groups, we excluded cases of vaginal delivery converted to caesarean delivery. Data was retrieved from case files on important variables in both groups for women and their newborns.

Management of delivery

In this hospital, it is a policy for an experienced obstetrician to be present for every VBD and to augment breech labour only with oxytocin in cases of dynamic dystocia. All deliveries occurred with women lying in the recumbent position with legs in holders. Foetal heart monitoring during labour is done electronically by means of a cardiotocography machine.

Data collection and variables.

- We identified the records of all women-newborn dynads for term singleton breech deliveries using the delivery registers. Their medical records were then retrieved from the hospital archives for data extraction. The variables studied were:
- Maternal demographic data: maternal age, marital status and profession.
- **Obstetric history:** parity and number of antenatal care visits.
 - Details of labour: foetal presentation, foetal heart rhythm, premature rupture of membranes, umbilical cord prolapse, uterine contractions, colour of amniotic fluid, duration of labour, episiotomy, perineal tears, APGAR score at the 5th minute and birth injuries, perinatal deaths.

 Postpartum complications: postpartum haemorrhage, urinary or faecal incontinence in women, and perinatal mortality for newborns.

Definition of terms

Brachial plexus injury was defined as any paralysis of the muscles of the shoulder girdle, arm, forearm of the newborn and occurring after dystocia (difficult childbirth). It was diagnosed by the attending obstetrician or midewife at birth and confirmed by a paediatrician during the first physical examination of the newborn within 24 hours of birth. Birth asphyxia was diagnosed based on the Modified Sarnat-Sarnat Score (15) and a five-minute Apgar score ≤ 3 associated with neurological signs such as hypotonia, coma or convulsions (16). The duration of labour was the estimated time period from 4 cm cervical dilatation to expulsion of the foetus. For all deliveries, this time interval was monitored and recorded on a partogram. Foetal Distress was defined as the occurrence of foeatal tachycardia (foetal heart beats ≥ 160 beats/min) or foetal bradycardia (≤ 110 beats/min) (17). PPH was defined as an estimated blood loss greater than 500 ml within 24 hours after vaginal delivery (18).

Data management and statistical analysis

Data was entered in Epi Info 7.1.3.3 software. Comparison of variables between pregnant women who had VBD and VCD was done using the Chi-square test or Fisher exact test where appropriate. Odds ratios (OR) and their corresponding 95% confidence intervals (95% CI) were calculated in order to measure associations. The original alpha-value was set at 0.05. In order to reduce the chance of obtaining a type 1 error from the multiple analyses performed on the same dependent variable, Bonferroni adjusted p-values were calculated by dividing the alpha-value by the number of comparisons. Hence, any comparison was statistically significant if it was inferior to the Bonferroni adjusted p-value.

Ethical consideration

- The study was approved by the Institutional Review Board of the Faculty of Medicine and
- Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon.

175 Results

Demographic and obstetrical characteristics

During the five-year review period, a total of 13, 695 deliveries were recorded. Among these deliveries, 364 breech deliveries occurred, giving an incidence of 26.6 per 1000 deliveries. After strict application of our eligibility criteria, we retained the files of 53 women with singleton term vaginal breech deliveries of babies weighing between 2500 - 3500g (Figure 1). Of the 53 VBD, 12 (22.6%) were unexpected breech births diagnosed during labour and nine (17%) vaginal breech births required forceps delivery mainly as a result of delayed expulsion of the after coming head. These women were matched to 212 women with singleton term VCD of newborns weighing between 2500 - 3500g during the same study period. There were 35 frank breech presentations (66%) and complete breech in 18 cases (34%). The maternal ages ranged from 15 to 45 years and the most frequent age group was 20 – 30 years (54.7%). Half had attended at least four antenatal care (ANC) visits, 54.7% were unemployed and 45.3% were married. Both VBD and VCD groups showed similarities in maternal age, parity, marital and employment status (table 1).

Maternal outcomes

Unlike paturients who had VCD, those who underwent VBD were more likely to have prolonged labour (OR: 8.05; 95% CI: 3.00-11.47; p <0.001), premature rupture of

193	membranes (OR: 2.14 ; 95% CI: $1.02-4.48$; $p = 0.04$), and postpartum haemorrhage (OR:
L94	3.07; 95% CI: 1.11-8.50; p = 0.03). After Bonferroni adjustment (p-value < 0.006), only
195	prolonged labour, meconium stained amniotic fluid and delivery by a midwife were retained
196	as determinants of adverse maternal outcomes of VBD (table 2).

Neonatal outcomes

Compared to babies born of VCD, counterparts (VBD group) were more likely to have foetal distress (OR: 2.05; 95% CI: 1.14-3.67; p = 0.0153), brachial plexus injury (OR: 3.91; 95% CI: 2.11-7.26; p = 0.0262), and about five-fold as likely to suffer from birth asphyxia (OR: 4.74; 95% CI: 3.09-7.26; p < 0.001). Only birth asphyxia was retained as an adverse neonatal outcome after Bonferroni correction (p < 0.0125) (table 3).

Discussion

This study aimed at determining the maternal and neonatal outcomes of vaginal breech delivery for singleton term pregnancies in a tertiary mother and child hospital in Yaounde, Cameroon. Despite the application of the aforementioned guidelines (4–6), VBD was found to be significantly associated with prolonged labour (OR: 8.05; 95% CI: 3.00-11.47; p <0.001), and birth asphyxia (OR: 10.24; 95% CI: 4.92-21.31; p <0.001). This observation could be the result of the high incidence of dystocia associated with this presentation (19).

The findings indicate that the perinatal mortality in VBD was comparable to that of VCD (2% vs 0%; p=0.2). This may be attributed to the fact that the study was carried out in referral hospital with an experienced obstetric team and with means of electronic foetal monitoring (cardiotocography) to timely detect warning signs of non-reassuring foetal status

during vaginal breech birth. These results are consistent with the studies reporting no difference in the perinatal mortality following breech delivery in resource-limited settings (20,21). On the other hand, Kemfang et al (22) in a similar study setting in Cameroon reported a significant perinatal mortality (p<0.01) for breech deliveries, which could be due to the absence of well-defined selection criteria for vaginal breech delivery in their series. Their observed perinatal mortality was in cases of macrosomia, nuchal extension, dystocic labour and placental abruption, which were all excluded in the current cohort.

Neonates delivered through breech birth were more likely to have birth asphyxia than those who had a vaginal cephalic birth (47% vs. 8%; p < 0.001), corroborating previous studies from both high-income (3,23) and low-income settings (20,21,24). This could be related to the fact that breech foetuses are predisposed to an increased risk of hypoxic-anoxic events from head entrapment, rapid decompression of the head, and other birth trauma (7).

The main limitation of this study was that being a retrospective study, data collection was subject to the potential risk of reviewing incorrectly completed records. Furthermore, less than four ANC visits were attended in 68% of VBD compared to 43% of VCD studied (p = 0.002). ANC attendance was not a matching variable between the VBD and VCD groups. Hence, the VBD cases were a higher risk group from the onset of the study and 22.6% of VBD were unrecognised before the onset of labour. Also, the study was conducted in an urban centre with standards of a tertiary level of care, which implies cautious generalization of our results to health facilities not having the same level of care. Nevertheless, based on careful selection criteria of singleton term VBD and the statistical analysis used to eliminate bias, we reviewed a five-year period to assess the outcomes of VBD in a low-income country where caesarean delivery cannot be generalized as the mode of delivery for all breech presentations because of its financial cost and the prevalent inadequate surgical infrastructure

in most health facilities. The findings are a significant contribution to the on-going debate on the safety of vaginal breech delivery in sub-Saharan Africa.

Conclusion

The findings suggest that even when breech delivery guidelines are applied, VBD of singleton term pregnancies is still associated with a high incidence of maternal and perinatal morbidity. This finding does not discount the role of VBD in resource-poor settings, but emphasises the need for rigorous monitoring of labour, timely decision and adequate anticipation for neonatal resuscitation in order to reduce these complications. Also, the practise of external cephalic version should be taught and promoted in this resource-limited setting as a means to convert breech to cephalic presentations and reduce the perinatal and maternal morbidities associated with VBD. Refresher courses for the management of breech birth should be organised for health personnel in order to minimize risk of brachial plexus injury. Based on the limitations of the study, there is a need to carry out large multicentre clinical trials in our resource-limited settings.

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Authors' contributions: JSD, PF and EM: Study conception and design, acquisition of data, data analysis and interpretation, manuscript writing and critical revisions. FM: Study conception and design, acquisition of data, data analysis and interpretation and manuscript writing. JNT, MNT, RT and VA: Acquisition of data, data analysis and interpretation, manuscript writing and revisions. All authors read and approved the final manuscript.

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors Competing interests: We have read and understood BMJ policy on declaration of interests and declare that we have no competing interests. Ethical Approval: The study was approved by the Institutional Review Board of the Faculty of Medicine and Biomedical Sciences, University of Yaounde I, Yaounde, Cameroon. **Data sharing statement:** No additional data are available. Figure and Table Legend Figure 1: Flow chart depicting selection of vaginal breech and cephalic delivery cases. Table 1: Socio-demographic characteristics and obstetric history of paturients Table 2: Maternal outcomes of vaginal breech delivery Table 3: Analysis of neonatal outcomes associated with vaginal breech delivery References Hickok DE, Gordon DC, Milberg JA, Williams MA, Daling JR. The frequency of breech presentation by gestational age at birth: a large population-based study. Am J Obstet Gynecol. 1992;166:851-2. Conde-Agudelo A, Belizán JM, Díaz-Rossello JL. Epidemiology of fetal death in Latin America. Acta Obstet Gynecol Scand. 2000;79:371-8. Hannah ME, Hannah WJ, Hewson SA, Hodnett ED, Saigal S, Willan AR, Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. Term Breech Trial Collaborative Group. Lancet Lond Engl. 2000;356:1375-83.

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Table 1: Socio-demographic characteristics and obstetric history of mothers

Groups	Number (%)	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	p-value
Maternal age groups (years)				
< 20	31 (11.7%)	6	25	0.3068
20 - 30	145(54.7%)	25	120	
30 - 40	85(32.1%)	20	65	
>40	4 (1.5%)	2	2	
Occupation*				
Unemployed	145 (54.7%)	31	114	0.3323
Employed	72 (27.2%)	10	62	
Self-employed	47 (18.1%)	11	36	
Marital status*	, ,			
Married	120 (45.3%)	28	96	0.4414
Single	117 (44.2%)	18	94	******
Cohabitation	27 (10.2%)	6	22	
Parity	27 (10.270)	O	22	
Nulliparous (parity = 0)	104 (39.3%)	18	86	0.6199
Primiparous (parity = 1)	60 (22.6%)	12	48	0.01
Multiparous (parity > 1)	101 (38.1%)	23	78	
Number of antenatal care visits ^f		23	70	
≥ 4	135 (51%)	17	115	0.002
< 4	127 (48%)	36	91	0.002
*1 missing data; ^β 3 missing data		30	91	

^{*1} missing data; ^β 3 missing data

Table 2: Maternal outcomes of vaginal breech delivery

Variables	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	Odds ratio	95% confidenc e interval	p-value
Premature rupture of					
membranes					
Yes	13 (24.5%)	28 (13%)	2.14	1.02-4.48	0.0448
No	40 (75.5%)	184 (87%)			
Umbilical cord prolapse					
Yes	2 (4%)	1 (0.5%)	8.27	0.74-93.05	0.087
No	51 (96%)	211 (99.5%)			
Prolonged labour (> 12					
hours)					
Yes	25 (47%)	28 (13%)	8.05	3.00-11.47	< 0.001
No	28 (53%)	184 (87%)			
Course of labour					
Augmented with oxytocin	2 (4%)	15 (7.1%)	0.52	0.11-2.33	0.3882
Spontaneous	51 (96%)	197 (92.9%)			
Episiotomies					
Yes	3 (5.7%)	22 (10.4%)	0.52	0.15-1.80	0.301
No	50 (94.3%)	190 (89.6%)			
Perineal tears					
Yes	17 (32%)	64 (30%)	1.09	0.57-2.09	0.7897
No	36 (68%)	148 (70%)			
Uterine atony					
Yes	1 (2%)	5 (2.4%)	0.79	0.09-6.96	0.8368
No	52 (98%)	207 (97.6%)			
Postpartum haemorrhage	. ,				
Yes	7 (13.2%)	10 (4.7%)	3.07	1.11-8.50	0.0305
No	46 (86.8%)	202 (95.3%)			

371 Bonferroni corrected p-value < 0.00625.

Table 3: Analysis of neonatal outcomes associated with vaginal breech delivery

	Vaginal breech delivery (n=53)	Vaginal cephalic delivery (n=212)	Odds Ratio	95% confidence interval	p-value
Foetal distress					
Yes	9 (17%)	15 (7%)	2.69	1.11-6.53	0.0293
No	44 (83%)	197 (93%)			
Neonatal asphyxia		, ,			
Yes	25 (47.2%)	17 (8.0%)	10.24	4.92-21.31	< 0.00
No	28 (52.8%)	195 (92%)			
Brachial plexus injury		` ′			
Yes	3 (5.7%)	01(0.5%)	12.66	1.28-124.28	0.0262
No	50 (94.3%)	211 (99.5%)			
Perinatal deaths		()			
Yes	1 (2%)	00	12.14	0.49-302.36	0.128
No	52 (98%)	212 (100%)			

Bonferroni corrected p-value < 0.0125.

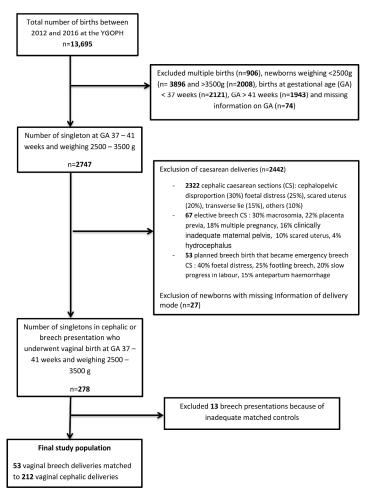


Figure 1: Flow chart depicting selection of vaginal breech and cephalic delivery cases.

Figure 1: Flow chart depicting selection of vaginal breech and cephalic delivery cases.

148x210mm (600 x 600 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 3 and 4
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 4
Methods			
Study design	4	Present key elements of study design early in the paper	Page 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Pages 5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Page 5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 6
Bias	9	Describe any efforts to address potential sources of bias	Page 6
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 7
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	Page 7
		(d) If applicable, explain how loss to follow-up was addressed	Page 7
		(e) Describe any sensitivity analyses	-
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed	Page 8
·		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 8
		(b) Indicate number of participants with missing data for each variable of interest	Page 8
		(c) Summarise follow-up time (eg, average and total amount)	Page 8
Outcome data	15*	Report numbers of outcome events or summary measures over time	Pages 8 and 9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	Pages 8 and 9
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	-
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	-
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 9
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	Pages 9 and 10
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	Not applicable
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.